K073177

510(k) Summary

MAY 13 2008

Sponsor:	Pioneer Surgical Technology 375 River Park Circle Marquette, MI 49855 Contact: Jonathan M. Gilbert (906) 226-4812
Device Name:	Pioneer Intervertebral Body Fusion System
Classification:	888.3080 Intervertebral Fusion Device with bone graft Classification Product Code: MAX Subsequent Product Code: ODP
Predicate Device:	The subject device is substantially equivalent to various cleared devices, including Pioneer's Vertebral Spacer - K061151, Medicrea's Impix K072226, IST's Paramount – K072120, and Synthes Spacer K072253 and P980048/BAK Cervical Interbody Fusion device.
Device Description:	The Pioneer Intervertebral Body Fusion device system is a radiolucent interbody fusion implant comprised of various heights and footprints to accommodate individual patient anatomy and graft material size. It is designed for use with supplemental internal fixation to provide structural stability in skeletally mature individuals.
Intended Use:	The Pioneer IBF device systems are indicated for intervertebral body fusion of the spine in skeletally mature patients. The device systems are designed for use with autogenous bone graft to facilitate fusion. One device may be used per intervertebral space. The implants are intended to be used with supplemental spinal fixation cleared for the implanted level, such as the Quantum, LowTop or SlimFuse systems. The Cervical IBF device is intended for use at one level in the cervical spine, from C3 to T1, for the treatment of cervical disc disease (defined at neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is to be used in patients who have had six weeks of non-operative treatment. The Lumbar IBF device system is also intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is to be used in patients who have had six months of non-operative treatment.
Material:	Radiolucent polymer and titanium alloy materials in conformance with ASTM Standard Specifications.
Basis of Substantial Equivalence:	Documentation was provided which demonstrated the Pioneer Intervertebral Body Fusion system to be substantially equivalent to previously cleared devices. The substantial equivalence is based upon equivalence in intended use, indications, anatomic sites, performance and material of manufacture.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 2008

Pioneer Surgical Technology
% Mr. Jonathan M. Gilbert
375 River Park Circle
Marquette, MI 49855

Re: K073177
Trade/Device Name: Pioneer Intervertebral Fusion Device System
Regulation Number: 21 CFR 888.3080
Regulation Names: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX, ODP
Dated: April 28, 2008
Received: April 30, 2008

Dear Mr. Gilbert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K073177

Device Name: Pioneer Intervertebral Fusion Device System

Indications for Use:

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The Cervical IBF device is intended for use at one level in the cervical spine, from C3 to T1, for the treatment of cervical disc disease (defined at neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is to be used in patients who have had six weeks of non-operative treatment.

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Prescription Use √ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices